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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/086,033	02/28/2002	Jon S. Wilson	4798-06A(17.1)	5173	
. 30166	7590 05/03/2002				
WOMBLE CARLYLE SANDRIDGE & RICE PLLC 300 N. GREENE STREET SUITE 1900 GREENSBORO, NC 27401			EXAM	EXAMINER	
			NICOLAS, FREDERICK C		
GREENSBOR	O, NC 27401		ART UNIT	PAPER NUMBER	
			3754		

Please find below and/or attached an Office communication concerning this application or proceeding.

S	D

Applicant(s)

	10/086,033	WILSON ET AL.				
Office Action Summary	Examiner	Art Unit				
	Frederick C. Nicolas	3754				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status						
1)⊠ Responsive to communication(s) filed on 28 F	ebruary 2002 .					
	is action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1-15 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-15</u> is/are rejected.						
7) Claim(s) is/are objected to.	- clastica resultantes					
8) Claim(s) are subject to restriction and/or Application Papers	r election requirement.					
9) The specification is objected to by the Examiner	r.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accep		niner.				
Applicant may not request that any objection to the	•					
11) The proposed drawing correction filed on	is: a)☐ approved b)☐ disappro	ved by the Examin	er.			
If approved, corrected drawings are required in rep	oly to this Office action.					
12) The oath or declaration is objected to by the Exa	aminer.					
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) S. Patent and Traformet's Office.	5) Notice of Informal F	(PTO-413) Paper No Patent Application (PT				

Application No.

Application/Control Number: 10/086,033

Art Unit: 3754

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the claimed subject matter "a second end" as recited in claim 1, line 11; in claim 7, line 19; in claim 9, line 19; in claim 10, line 19; in claim 12, line 20; in claim 14, line 8, and in claim 15, line 9.

Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- I- As to claim 1, line 11, it is unclear by what is meant by "the distal portion of the catheter tube exiting through <u>a second end</u>"; further, which area is considered to be the second end?
- II- As to claim 7, line 19, it is unclear by what is meant by "the distal portion of the catheter tube exiting through <u>a second end</u>"; further, which area is considered to be the second end.
- III- As to claim 9, line 19, it is unclear by what is meant by "the distal portion of the catheter tube exiting through <u>a second end</u>"; further, which area is considered to be the second end.

Application/Control Number: 10/086,033

Art Unit: 3754

IV- As to claim 10, line 19, it is unclear by what is meant by "the distal portion of the catheter tube exiting through <u>a second end</u>"; further, which area is considered to be the second end.

V- As to claim 12, line 20, it is unclear by what is meant by "the distal portion of the catheter tube exiting through <u>a second end</u>", further, which area is considered to be the second end.

VI- As to claim 14, line 8, it is unclear by what is meant by "the distal portion of the catheter tube exiting through <u>a second end</u>", further, which area is considered to be the second end.

VII- As to claim 15, line 9, it is unclear by what is meant by "the distal portion of the catheter tube exiting through <u>a second end</u>", further, which area is considered to be the second end.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 5. Claims 1,14-15, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Maginot (U.S 5,989,213).

Maginot discloses a method for inserting a multi-lumen catheter assembly into an area to be catheterized as best seen in Figure 7, the multi-lumen catheter assembly (16) having a multi-lumen catheter tube (32), the tube has a proximal portion and a



Application/Control Number: 10/086.033

Art Unit: 3754

distal portion see Figure 3 for location, an attachable hub assembly (48) having a hub body with a distal portion and a proximal portion see Figure 5A for location (note: it is inherent that the hub assembly has a hub body), the method comprises the steps of: making an incision near the area to be catheterized (column 11, lines 22-26), inserting the proximal portion of the multi-lumen catheter tube into the area to be catheterized as best seen in Figure 7, creating a subcutaneous tunnel (column 11, lines 22-24), where a first end of the subcutaneous tunnel is near the incision near the area to be catheterized (column 11, lines 24-26), routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through a second end of the subcutaneous tunnel (column 11, lines 26-52), and attaching the proximal portion of the hub body to the distal portion of the catheter tube (column 11, lines 60-67 onto column 12, lines 1-16).

Allowable Subject Matter

- Claims 2-6 are objected to as being dependent upon a rejected base claim, but 6. would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- Claims 7-13 would be allowable if rewritten or amended to overcome the 7. rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Conclusion

The prior art made of record and not relied upon is considered pertinent to 8. applicant's disclosure. Ash et al., Winters et al., Hadford et al., Martin et al., Fenton, Jr. et al., Setzer et al., Dadson et al., Maginot et al. (U.S 6,190,371), Trotta, Tesio, Markel

Page 5

Application/Control Number: 10/086,033

Art Unit: 3754

et al., Maginot (U.S 6,156,016), Martin (U.S 5.053,023), Pinchuk, Miller et al., Howell et al., Martin (U.S 5,472,432), Cameron, Bates (U.S 4,643,711), Bates (U.S 4,772,268), Mahurkar, Fulton, McGuckin, Jr., Palestrant, Twardowski et al. and Fleming, III disclose other types of method for inserting a multi-lumen catheter assembly.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick C. Nicolas whose telephone number is (703)-305-6385. The examiner can normally be reached on Monday - Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry C. Yuen, can be reached on (703) 308-1946. The fax phone number for the organization where this application or proceeding is assigned is (703)-308-7766.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0861.

FN May 1, 2002

5/1/02

Lesley D. Morris
Primary Examiner

Au3752